

## R E M A R K S

In response to the Official Action of 30 July 2002, wherein the Examiner has required restriction under 35 USC 121 and 372, Applicants hereby elect to prosecute in the present application the invention of Group I with traverse. The reasons for the traversal are next discussed.

Under PCT unity of invention rules, unity of invention has to be considered in the first place only in relation to the independent claims in an application and not the dependent claims. If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims (see Annex B to Administrative Instructions Under the PCT).

In the present case, the Examiner apparently does not consider the independent claim (Claim 11) to avoid the prior art on the basis that the cited Foster et al reference allegedly destroys novelty of the claimed invention. Applicants respectfully disagree. Claim 11 is directed to a method of treating liver diseases [marked by lower than normal levels of IFN-alpha 5]. There is nothing in the reference that would even show or suggest that IFN-alpha 5 (or any other interferon-alpha subtype) is or should be expressed in liver tissue of a patient (healthy or otherwise). Accordingly, there is nothing in the reference that could show or suggest administering IFN-alpha to a patient [having lower than normal levels of IFN-alpha 5].

*arguing  
liver  
not originally  
Claim 11*

Moreover, Foster et al show only that several subtypes of IFN have anti-viral activity, but not that this would translate into effectiveness in administering any specific

interferon subtype to treat a human disease of viral origin. Indeed, the reference only shows the anti-viral activity of interferon subtypes with respect to EMC virus (note: the antiviral assays described on page 1028 of the reference use an encephalomyelitis murine virus). Moreover, the cells used in the assay were liver tumor cells and the reference thus could not show anything about the activity of any interferon subtype in normal liver cells of a patient.

In fact, the Foster et al reference makes clear that the role of the described interferon subtypes and the possibility for their use in treating any particular viral disease in any specific organ is hypothetical at best (see Foster et al at page 1032, column 2, first full paragraph). It is thus clear that the reference disclosure could not be used to provide even a reasonable expectation of success with the claimed method. Accordingly, the reference not only does not anticipate the invention defined by the independent claims, it does not render such claims *prima facie* obvious.

In view of the above, it is respectfully submitted that the independent claims presently of record avoid the prior art and satisfy the requirement of unity of invention. Accordingly it is respectfully submitted that all claims presently on file should be examined in this application.

Respectfully submitted,

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11. (Amended) A method for treating a patient having a liver disease of viral origin, said disease being marked by lower than normal levels of IFN-alpha 5, said method comprising a step of administering to the patient an amount of IFN-alpha 5 or a nucleotide sequence encoding IFN-alpha 5 that is effective to treat the disease.